Bioinformatics Integration Support Contract (BISC), Phase II

MINIMUM CLINICAL INFORMATION FOR DATA ARCHIVES

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BACKGROUND

This document is intended to detail the minimum study data that should be collected from Clinical Research Organizations (CRO's) at the completion of DAIT funded studies that were not previously targeted for ImmPort data sharing. The collection of this minimum information improves the likelihood that enough metadata has been provided to allow the BISC team to load the given study into ImmPort for later query and retrieval by other researchers.

MINIMUM INFORMATION

In order to ensure that the data retrieved by the CRO during the study conduct and analysis can be interpreted by future researchers, some minimum study metadata must be provided to provide appropriate context. It is assumed that the CRO will already be providing SAS transport (or data) files containing the clinical study results.

1. Study Protocol: The Study protocol document provides background information about the study design and accompanying information, generally including:
    a. Study title, description, objectives and end points
    b. Arm or cohort definition
    c. Study personnel
    d. Enrollment criteria
    e. Visit Plan and Event Plan
    f. Event Panels
    g. Subject Measure Definitions
2. Case Report Forms (CRF's): The Case Report Forms and preferably a mapping between the CRF questions and answers and the SAS data set (e.g., annotated CRF forms)provides context and allows the BISC team to map SAS result tables to defined data columns in the ImmPort data model.
3. Data Dictionary for the SAS data tables: If available, a field name and description would be helpful in performing the mapping exercise between the SAS data files and defined columns in the ImmPort data model.
4. Mechanistic assay results: A catalog of the experiments run with the assay platform used, the subjects that were tested along with the appropriate study day from which the source sample was drawn, and the result files for each result along with the protocols should be provided if DAIT wishes re-analysis of this data to be possible from within or outside the ImmPort resource after the data is shared to the larger community. It must be possible by some method to associate the subjects that were tested with the result files (e.g., subject ids in the files, subject ids embedded in result file names, a file associating subject ids with result file names, etc.). The CRO should provide an explanation of how this association is established.
5. An association of study subject with ARMs or cohorts. This may be either an explanation of how the association is shown in SAS files provided for the study, or may be provided as a file associating study defined subject ids with arms or cohorts of the study.
6. If any derived data is included in the data delivery (e.g., statistical analysis of assessments) then the computations performed on the base data in order to generate the derived data need to be defined.